# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT** 

Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 13, 2017

### ANI PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)

001-31812 (Commission File Number) 58-2301143 (I.R.S. Employer Identification Number)

210 Main Street West Baudette, Minnesota (Address of principal executive offices) 56623 (Zip Code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the

Registrant's telephone number, including area code: (218) 634-3500

follo	wing provisions (see General Instruction A.2. below):
	Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
	Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
	Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
	Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 7.01 Regulation FD Disclosure.

On March 13, 2017, ANI Pharmaceuticals, Inc. (the "Company," "we" or "us") posted to its website its March 2017 Corporate Presentation. We may use this presentation in our communications or at conferences. The presentation is available on our website, www.anipharmaceuticals.com, and is attached to this Current Report on Form 8-K as Exhibit 99.1 and incorporated into this Item 7.01 by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

#### **Forward-Looking Statements**

Exhibit No.

99.1

Certain statements contained in the presentation slides furnished with this report contain forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about future operations, products, financial position, operating results, prospects, pipeline or potential markets therefor, and other statements that are not historical in nature, particularly those that utilize terminology such as "anticipates," "will," "expects," "plans," "potential," "future," "believes," "intends," "continue," other words of similar meaning, derivations of such words, and the use of future dates.

Uncertainties and risks may cause our actual results to be materially different than those expressed in or implied by such forward-looking statements. Uncertainties and risks include, but are not limited to, the risk that we may face with respect to importing raw materials, increased competition, acquisitions, contract manufacturing arrangements, delays or failure in obtaining product approval from the U.S. Food and Drug Administration ("FDA"), general business and economic conditions, market trends, product development, regulatory and other approvals and marketing.

More detailed information on these and additional factors that could affect our actual results are described in our filings with the Securities and Exchange Commission, including our most recent annual report on Form 10-K and quarterly reports on Form 10-Q, as well as our proxy statement/prospectus, filed with the Securities and Exchange Commission on April 14, 2016. The forward-looking statements contained in this document are made only as of the date of

this doc otherwi		Te undertake no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or
Item 9.	01.	Financial Statements and Exhibits.
(d)	Exhibits	
Exhibit	No.	Exhibit

ANI Pharmaceuticals, Inc. Corporate Presentation March 2017

#### **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ANI PHARMACEUTICALS, INC.

Date: March 14, 2017 By: /s/ Stephen P. Carey

Stephen P. Carey

Vice President, Finance and Chief Financial Officer



# A Specialty Pharmaceutical Company NASDAQ: ANIP

GENERIC AND BRANDED PRESCRIPTION DRUG PRODUCTS

Corporate Presentation

March 2017

### Forward-Looking Statements

To the extent any statements made in this presentation deal with information that is not historical, these are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about price increases, the Company's future operations, products financial position, operating results and prospects, the Company's pipeline or potential markets therefore, and other statements that are not historical in nature, particularly those that utilize terminology such as "anticipates," "will," "expects," "plans," "potential," "future," "believes," "intends," "continue," other words of similar meaning, derivations of such words and the use of future dates.

Uncertainties and risks may cause the Company's actual results to be materially different than those expressed in or implied by such forward-looking statements. Uncertainties and risks include, but are not limited to, the risk that the Company may face with respect to importing raw materials; increased competition; acquisitions; contract manufacturing arrangements; delays or failure in obtaining product approval from the U.S. Food and Drug Administration; general business and economic conditions; market trends; products development; regulatory and other approvals and marketing.

More detailed information on these and additional factors that could affect the Company's actual results are described in the Company's filings with the Securities and Exchange Commission, including its most recent annual report on Form 10-K and quarterly reports on Form 10-Q, as well as its proxy statement. All forward-looking statements in this presentation speak only as of the date of this presentation and are based on the Company's current beliefs, assumptions, and expectations. The Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.



## Mission and Strategy

ANI Pharmaceuticals is an integrated specialty pharmaceutical company focused on delivering value to our customers by developing, manufacturing and marketing high quality branded and generic prescription pharmaceuticals.

Our dedicated team of R&D, business development, manufacturing, sales, and regulatory compliance personnel focus on niche and high barrier to entry opportunities, including controlled substances, anti-cancer (oncolytics), hormones and steroids, and complex formulations.

We manufacture diverse product offerings in two facilities with combined manufacturing, packaging, warehouse and laboratory space totaling 116,000 square feet.



# Senior Management Team

		With ANI Since	Yrs Industry Experience	Previous Affiliation
Arthur Przybyl	President and CEO	2009	25+	Akorn
Stephen Carey	VP, Finance and CFO	2016	20+	Par Pharmaceutical
Robert Schrepfer	SVP, Business Development and Specialty Sales	2013	15	Healthcare Value Capital
James Marken	SVP, Operations and Product Development	2007	20+	Solvay
David Sullivan, PhD	VP, Quality Operations	2014	20	Boston Scientific
Ellen Camos	VP, Regulatory Affairs	2012	15	Sandoz
Mark Ginski, PhD	VP, Corticotropin Product Development	2016	20+	Mallinckrodt
Karen Quinn, PhD	VP, Corticotropin Regulatory Affairs	2017	30+	Takeda Pharmaceuticals



### Financial Highlights - 4Q and Full Year 2016

(\$ in millions, except per share data)	hree Mon <u>Decem</u> 2016	ber 3		Year <u>Decem</u> 2016	
Net revenues	\$ 38.2	\$	18.0	\$ 128.6	\$ 76.3
Net (loss) / income	\$ (1.1)	\$	2.9	\$ 3.9	\$ 15.4
GAAP (loss) / eamings per diluted share	\$ (0.09)	\$	0.25	\$ 0.34	\$ 1.32
Adjusted non-GAAP EBITDA (1)	\$ 17.9	\$	9.5	\$ 61.1	\$ 43.5
Adjusted non-GAAP net income per diluted share (1)	\$ 0.84	\$	0.52	\$ 3.78	\$ 2.72

Record annual results on the strength of new product launches during 2016:

- 25 commercial product families, up from 16 at the beginning of 2016
- Net revenues increased 112% from prior year in 4Q and 69% on full year basis
- Adjusted non-GAAP EBITDA increased 88% from prior year in 4Q and 41% on full year basis



(1) See Appendix A for US GAAP reconciliations

# Financial Highlights - 4Q Net Revenues

(\$ in millions)		nree Mor Decem				Variance to Prior Year			
	3	2016		2015		<u>\$</u>	<u>%</u>		
Generic pharmaceutical products	\$	29.3	\$	14.0	\$	15.2	109%		
Brand pharmaceutical products		6.5		2.3		4.2	179%		
Contract manufacturing		1.6		1.3		0.3	19%		
Contract services and other income	<u> </u>	8.0		0.3	8 <u> </u>	0.5	143%		
Total net revenues	\$	38.2	\$	18.0	\$	20.2	112%		

- Generic sales gains driven by products launched during 2016 (detailed on slide 11)
- Brand sales reflect April 2016 launch of Inderal® LA



Note: Figures may not foot / cross-foot due to rounding.

# Financial Highlights - 2016 Net Revenues

(\$ in millions)		Year l				Variance to Prior Year		
Li Anto Control and Control Co		<u> 2016</u>	<u>2015</u>		<u>\$</u>		<u>%</u>	
Generic pharmaceutical products	\$	95.2	\$	55.2	\$	40.0	73%	
Brand pharmaceutical products		26.4		11.0		15.4	140%	
Contract manufacturing		5.5		4.9		0.7	13%	
Contract services and other income		1.4		5.3	-	(3.8)	-73%	
Total net revenues	\$	128.6	\$	76.3	\$	52.3	69%	

- Generic sales gains driven by products launched during 2016 (detailed on slide 11)
- Brand sales reflect April 2016 launch of Inderal® LA
- Contract manufacturing reflects timing and volume of customer orders
- Contract services and other previously reflected royalty income on authorized generic of Vancocin®, which is now sold directly by ANI and reflected in Generic sales



Note: Figures may not foot / cross-foot due to rounding.

### 2017 Guidance

(\$ in millions except EPS figures)

5 E ST. 10		2016		2017 Gu	ıi da	nce	% Incr	ease
	<u>A</u>	ctual	8	Low		<u>High</u>	Low	<u>Hi qh</u>
Net Revenues	\$	128.6	\$	181.0	\$	190.0	41%	48%
Cost of sales as a percentage of revenues (excluding impact of inventory step-up)		33%		42%		44%	n/a	n/a
Sales, general and administrative		27.8		30.2		30.9	8%	11%
Research and development		2.9		6.5		6.8	125%	134%
Adjusted non-GAAP EBITDA (1)		61.1		73.1		77.2	20%	26%
Adjusted non-GAAP diluted earnings per share (1)	\$	2.96	\$	3.58	\$	3.94	21%	33%

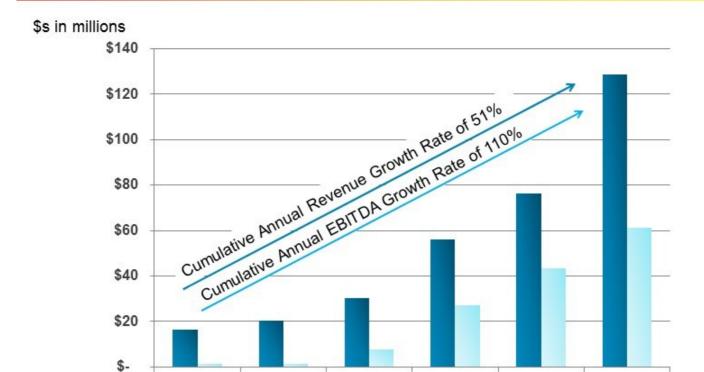
#### Forecast results projected to be driven by:

- Annualization and continued operational focus on maximizing 2016 launches
- Expansion of our brand revenues with the addition of InnoPran XL® and Inderal® XL
- Execution of 2017 generic product launches
- Increasing the investment behind our Corticotropin re-commercialization project



(1) See Appendix A for note regarding US GAAP reconciliations

### Historical 5-Year Revenue and Adjusted EBITDA Growth



Revenues

EBITDA



# Sales and Marketing Overview





# Generic Rx Product Portfolio 2016 Product Introductions

- Erythromycin
   Ethylsuccinate
- Fenofibrate Capsules (AG)
- HC Cream, for rectal use
- Lithium Carbonate ER (AG)

- Mesalamine Enema (AG)
- Nilutamide Tablets
- Oxycodone Capsules
- Propranolol ER Capsules (AG)



### Continued broadening of our product offerings

- Twenty generic product families encompassing 40 SKUs
- \$95.2 million of generic net sales in 2016



(AG) = Authorized Generic

# Generic Rx Product Portfolio Foundational Products (launched prior to 2016)

- EE/MT Tablets
- Etodolac Capsules
- Flecainide Tablets
- Fluvoxamine Maleate Tablets (AG)
- HC Enema (AG)
- Methazolamide Tablets

- Metoclopramide Solution
- Nimodipine Capsules
- Opium Tincture
- Oxycodone Oral Solution
- Propafenone Tablets
- Vancomycin Capsules (AG)



(AG) = Authorized Generic

### Brand Rx Product Portfolio



Inderal® LA Capsules Hypertension



Lithobid® Tablets Bipolar Disorder



Vancocin® Capsules C. difficile-Associated Diarrhea



Cortenema® Ulcerative Colitis



Reglan® Tablets Gastroesophageal Reflux

- Inderal® LA launched April 2016
- \$26.4 million of brand net sales in 2016



# Brand Rx InnoPran XL® and Inderal® XL





Two additional hypertension brands added in first quarter 2017:

- Purchased on February 23, 2017, for approximately \$51 million
- Generated combined sales of \$23.3 million in 2016 according to IMS Health data (gross sales basis)



# Contract Manufacturing and Other

- Contract manufacturing
  - \$5.5 million of 2016 net revenues
  - Four customers
    - Seven products and seventeen SKUs
    - Contract manufacturing and contract packaging
- Contract services and other
  - \$1.4 million of 2016 net revenues
  - Product development services, laboratory services, and royalties received



# Business and Product Development Overview





# Business Development Activity - Generics

252		STRUCTURE	SOURCE	STRATEGY	ANI MANUF	APPROVED	COST (\$M)
G e	Rowasa AG (Partnership with Meda)	US Distr Rights	Private	<b>✓</b>	$\checkmark$	$\checkmark$	\$0.0
	Lipofen AG & 1% and 2.5% HC Cream	Acquisition of US Distr Rights	Private	$\checkmark$		$\checkmark$	\$10.0
n	IDT Partnership (18 previously approved ANDAs)	US Distr Rights	Private	<b>√</b>	$\checkmark$	$\checkmark$	\$1.0
e r	Nimodipine & Omega (Partnership with Sofgen)	US Distr Rights	Private	<b>✓</b>			\$1.1
i	Flecamide (flecamide tablets)	Acquisition	Private	<b>✓</b>	$\checkmark$	$\checkmark$	\$4.5
3	ANDA Basket 1 (31 previously approved ANDAs)	Acquisition	Public	<b>✓</b>	<b>√</b>	<b>√</b>	\$12.5
	ANDA Basket 2 (22 previously approved ANDAs)	Acquisition	Public	<b>✓</b>	<b>✓</b>	<b>✓</b>	\$25.0
		,				Total	\$54.1



# Business Development Activity - Brands

		STRUCTURE	SOURCE	STRATEGY	ANI MANUF	APPROVED	COST (\$M)
	Inderal® XL (propranolol ER capsules)	Acquisition	Private	<b>✓</b>		<b>✓</b>	\$20.0
В	Inno Pran XL® (propranolol ER capsules)	Acquisition	Private	<b>✓</b>		<b>✓</b>	\$31.0
	Brethine® (terbutaline tablets)	Acquisition	Private	<b>✓</b>	<b>✓</b>	✓	\$0.0
a	Inderal® LA (propranolol ER capsules)	Acquisition	Private	<b>✓</b>		<b>✓</b>	\$60.0
n d	Cortico trophin® (cortico trop in injectable)	Acquisition	Public	<b>✓</b>		<b>✓</b>	\$75.0
s	Testosterone Gel (testosterone gel satchets)	Acquisition	Private	<b>✓</b>		$\checkmark$	\$0.0
	Vancocin® (vancomycin hydrochloride capsules)	Acquisition	Private	<b>✓</b>		<b>√</b>	\$11.0
	Lithobid® (lithium carbonate tablets)	Acquisition	Private		<b>✓</b>	<b>√</b>	\$12.0
						Total	\$209.0



### Product Development Pipeline

### ANI Pipeline

- 78 products in development, total combined current market: \$3.7 billion<sup>(1)</sup>
- 54 products were acquired and of those, ANI believes 47 can be commercialized based on either a CBE-30 or PAS

#### Corticotropin Re-commercialization Update

- Expert team assembled across key functions
- Dedicated lab established for analytical method development
- Identified, initiated, and continuing to make substantial progress toward the development of analytical methods required for the sNDA filing
- Porcine pituitary supply secured for small and commercial scale API
- API manufacturer secured; in fourth quarter of 2016 initiated manufacturing of R&D development batches of API



(1) Based on Company estimates, and recent IMS and NSP Audit data

# Manufacturing Overview





# Manufacturing - Main Street Facility

- Location: Baudette, Minnesota
  - 52,000 sq. ft. of manufacturing, packaging, and warehouse facilities
  - Rx solutions, suspensions, topicals, tablets, and capsules
  - DEA-licensed for Schedule II controlled substances
  - 17,000 square feet of laboratory space for product development and analytical testing
  - Expanding the warehouse by 5,500 square feet and adding additional schedule CII vault and CIII cage space
  - 2017 cap ex also includes powder fill line, liquid unit dose filling line, liquid packaging line, machinery and equipment upgrades and serialization capabilities





# Manufacturing – IDC Road Facility

- Location: Baudette, Minnesota
  - Fully-contained high potency facility with capabilities to manufacture hormone, steroid, and oncolytic products
  - 47,000 square feet of manufacturing, packaging, and warehouse facilities
  - 100 nano-gram per eight-hour time weighted average maximum exposure limit to ensure employee safety
  - DEA Schedule IIIN capability
  - Adding a low-humidity suite for processing and encapsulating moisture-sensitive compounds





### Summary

- ANI is an integrated specialty generic pharmaceutical company with:
  - Profitable base business generating organic growth
  - Strong capital position
  - Experienced management team
  - US-based manufacturing assets and expertise
  - 2017 Annual guidance<sup>(1)</sup>
    - Net revenues of \$181 million to \$190 million
    - Adjusted non-GAAP EBITDA<sup>(2)</sup> of \$73.1 million to \$77.2 million
    - Adjusted non-GAAP diluted earnings per share<sup>(2)</sup> of \$3.58 to \$3.94
- ANI is focused on delivering value through:
  - Partnerships and strategic alliances
  - Accretive acquisitions
  - Internal product development



(1) March 2, 2017 press release

(2) See Appendix A for note regarding US GAAP reconciliations

# Appendix A





### ANI Pharmaceuticals, Inc. and Subsidiaries Adjusted non-GAAP EBITDA Calculation and US GAAP to Non-GAAP Reconciliation

(unaudited, in thousands)

	Thre	e Months End 2016	led De	cember 31, 2015	Year Ended December 31, 2016 2015			
Net (Loss)/Income		(1,080)	\$	2,876	\$	3,934	\$	15,375
Add back								
Interest expense, net		2,859		2,768		11,327		11,008
Other income/(expense), net		43		(1)		74		(41)
(Benefit)/Provision for income taxes		(524)		625		4,744		6,358
Depreciation and amortization		5,812		2,111		22,343		6,900
Intangible asset impairment charge		6,685				6,685		_
Add back								
Stock-based compensation		1,380		1,139		6,067		3,856
Excess of fair value over cost of acquired inventory	80	2,758	80	3.5.22	58	5,938	151	-
Adjusted non-GAAP EBITDA	\$	17,933	\$	9,518	\$	61,112	\$	43,456



#### ANI Pharmaceuticals, Inc. and Subsidiaries

Adjusted non-GAAP Net Income and Adjusted non-GAAP Diluted Earnings per Share Reconciliation (New Methodology)

(unaudited, in thousands, except per share am ounts)

	Ended		Three Months Ended		Three Months Ended		Three Months Ended		Year Ended	
	Marci	h 31, 2016	June	30, 2016	Septem	nber 30, 2016	Decem	ber 31, 2016	Decem	ber 31, 2016
Net Income/(Loss)	s	1,346	S	1,125	S	2,543	S	(1,080)	s	3,934
Add back										
Excess of fair value over cost of acquired inventory		-		2,078		1,102		2,758		5,938
Non-cash interest expense		1,725		1,757		1,782		1,784		7,048
Stock-based compensation		1,105		2,217		1,365		1,380		6,067
Depreciation and amortization expense		4,609		5,958		5,968		5,812		22,343
Intangible as set impairment charge				-		-		6,685		6,685
Less										
Tax impact of adjustments	S <del></del>	(2,752)	100	(4,443)		(3,780)	-	(6,815)	× <del></del>	(17,790)
Adjusted non-GAAP Net Income	s	6,033	s	8,690	s	8,978	s	10,524	s	34,225
Diluted Weighted-Average										
Shares Outstanding		11,489		11,541		11,625		11,635		11,573
Adjusted non-GAAP	100				88	100	200	100		
Diluted Earnings per Share	S	0.53	S	0.75	S	0.77	S	0.90	S	2.96



#### ANI Pharmaceuticals, Inc. and Subsidiaries

Adjusted non-GAAP Net Income and Adjusted non-GAAP Net Income per Diluted Share Reconciliation (Previous Methodology)

(unaudited, in thousands, except per share amounts)

	Three	MonthsEnd	ed Dec	ember 31,	Year Ended December 31,				
	<u> </u>	2016		2015	9 <u>8</u>	2016		2015	
Net (Loss)Income	\$	(1,080)	\$	2,876	\$	3,934	\$	15,375	
Add back									
(Benefit)/Provision for income taxes		(524)		625		4,744		6,358	
Depreciation and amortization expense		5,812		2,111		22,343		6,900	
Intangible asset impairment charge		6,685		20		6,685		20	
Non-cash interest expense		1,784		1,722		7,048		6,831	
Stock-based compensation		1,380		1,139		6,067		3,856	
Excess of fair value over cost of acquired inventory		2,758		-		5,938		-	
Less									
Current Provision	-	(6,993)	727	(2,431)	3.5	(13,038)		(7,875)	
Adjusted non-GAAP Net Income	\$	9,822	\$	6,042	\$	43,721	\$	31,445	
Diluted Weighted-Average									
Shares Outstanding		11,635		11,552		11,573		11,557	
Adjusted non-GAAP									
Net Income Per Diluted Share	S	0.84	S	0.52	S	3.78	\$	2.72	



#### Non-GAAP Financial Measures included in 2016 Guidance

The Company's fiscal 2017 guidance for adjusted non-GAAP EBITDA and adjusted non-GAAP diluted earnings per share is not reconciled to the most comparable GAAP measure. This is due to the inherent difficulty of forecasting the timing or amount of items that would be included in a reconciliation to the most directly comparable forward-looking GAAP financial measures. Because a reconciliation is not available without unreasonable effort, it is not included in this presentation.

